K071996

AUG - 3 2007

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

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Contact Person: Allison Scott

Date: July 20, 2007

807.92(a)(2)

Trade Name: MyLab30 System

Common Name: Ultrasound Imaging System

Classification Name(s): Ultrasonic pulse doppler imaging system 892.1550
Ultrasonic pulsed echo imaging system 892.1560

Classification Number: 90IYN; 90IYO

807.92(a)(3)

Predicate Device(s)

K040596 K052805 K060827	7300 (MyLab30)	Esaote, S.p.A.
K033367	MicroMaxx	SonoSite

807.92 (a)(4)

Device Description

The 7300 (MyLab30) ultrasound system is used to perform diagnostic general ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, Doppler, 3D/4D and Color Flow Mapping and, on lower frequency probes, Tissue Enhancement Imaging (TEI). The systems are equipped with an optional LCD Color Display and can drive phased (PA), convex (CA) and linear array (LA) and Doppler probes.
The MyLab30 system is able to produce Real Time 2D images and 3D images (in manual mode) with all probes. The system, in combination with the BC431 or BS230 probes, offers the possibility to also produce automatic 3D and Real Time 4D images. The 7300 (MyLab30) is manufactured under an ISO 9001:2000 and ISO 13485 certified quality system.

807.92(a)(5)

Intended Use(s)

Esaote's Model 7300 (MyLab30) is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative: Abdominal, and Other: Urologic. The system provides imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

807.92(a)(6)

Technological Characteristics

The difference between the MyLab30 system cleared via K040596, K052805, K060827 and the MyLab30 system to be cleared via this 510(k) is that in this 510(k), the system provides imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2007

Esaote, S. p. A.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K071996
Trade Name: MyLab30 (Model 7300)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, IYN, and ITX
Dated: July 25, 2007
Received: July 26, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the MyLab30 (Model 7300), as described in your premarket notification:

Transducer Model Number

LA523
CA123

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the

Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

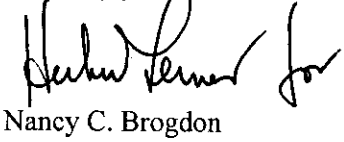
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Paul Hardy at (240) 276-3666.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known):

Device Name: MyLab30 Ultrasound System

Indications For Use:

Esaote's Model 7300 (MyLab30) is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative: Abdominal, and Other: Urologic. The system provides imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K071996

Diagnostic Ultrasound Indications for Use Form

Model 7300 (MyLab30)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P		P [2]	P [3], P[4]
Abdominal		P	P	P		P	P		P [2]	P [3], P[4]
Intraoperative (Abdominal)		P	P	P		P	P		P [2]	P [3]
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P [2]	P [3], P[4]
Small Organ (specify) [1]		P	P	P	P	P	P		P [2]	P [3]
Neonatal Cephalic		P	P	P	P	P	P		P [2]	
Adult Cephalic		P	P	P	P	P	P		P [2]	
Cardiac		P	P	P	P	P			P [2]	P [3], P[4]
Transesophageal		P	P	P	P	P	P		P [2]	
Transrectal		P	P	P		P	P		P [2]	
Transvaginal		P	P	P		P	P		P [2]	
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P	P	P	P		P [2]	
Laparoscopic										
Musculo-skeletal Conventional		P	P	P	P	P	P		P [2]	
Musculo-skeletal Superficial		P	P	P	P	P	P		P [2]	
Other (Urological)		P	P	P	P	P	P		P [2]	

N=new indication; P=previously cleared by FDA; E= added under Appendix E

Additional Comments:

[1] Small organs include Thyroid, Breast and Testicles.

[2] Applicable combined modes: B+M+PW+CW+CFM+PD

[3] Tissue Enhancement Imaging (TEI)

Compound Imaging

VPAN

Tissue Velocity Mapping (TVM)

CMM

CnTI

[4] 3D/4D Imaging

Included in this 510(k) is an expanded intended use for imaging guidance for peripheral nerve block procedures. Also included in this 510(k) is imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

(PLEASE DO NOT WRITE BELOW THIS LINE/CONTINUE ON ANOTHER PAGE IF NEEDED

concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K071996

Diagnostic Ultrasound Indications for Use Form

Transducer: LA523

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		P[1]	P[3]; P[4]
Small Organ (specify) [2]		P	P	P		P	P		P[1]	P[3]; P[4]
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P		P[1]	P[3]; P[4]
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		P[1]	P[3]; P[4]
Musculo-skeletal Superficial		P	P	P		P	P		P[1]	P[3]; P[4]
Other (specify)										

N=new indication; P=previously cleared by FDA; E= added under Appendix E

Additional Comments:

[1] Applicable combined modes: B+M+PW+CFM+PD

[2] Small organs include Thyroid, Breast and Testicles.

[3] Tissue Enhanced Imaging (TEI); [4] 3D Freehand

Included in this 510(k) is an expanded intended use for imaging guidance for peripheral nerve block procedures. Also included in this 510(k) is imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K071996

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD (PW)	CWD	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (1)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		P(1)	P[3]; P[4]
Small Organ		P	P	P		P	P		P (1)	P[3]; P[4]
Neonatal Cephalic		P	P	P		P	P		P (1)	P[3]; P[4]
Adult Cephalic										
Cardiac		P	P	P		P	P		P(1)	P[3]; P[4]
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P		P (1)	P[3]; P[4]
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		P (1)	P[3]; P[4]
Musculo-skeletal Superficial		P	P	P		P	P		P (1)	P[3]; P[4]
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: 1) Applicable combined modes: B+PW+CFM+M+PD;3) Tissue Enhanced Imaging (TEI); [4] 3D Freehand

Included in this 510(k) is an expanded intended use for imaging guidance for peripheral nerve block procedures. Also included in this 510(k) is imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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